

KNEE ORTHOSIS AND ORTHOTIC METHOD

FIELD OF THE INVENTION

5 The present invention relates to a knee orthosis and orthotic method. More particularly, the present invention relates to a knee orthosis and orthotic method that creates medial traction forces in the patellofemoral joint to reduce pain, increase function and speed rehabilitation.

BACKGROUND OF THE INVENTION

10 The patellofemoral joint of the knee is an articulating joint between the patella and the femur. More specifically, this joint consists of an articular surface on the posterior of the patella and a corresponding articular surface on the anterior distal portion of the femur, also termed the trochlear groove. The posterior of the patella is contoured as a ridge, while the trochlea is contoured as a groove that is
15 dimensioned to receive the patellar ridge in a complementary manner. Proper dynamic function of the patellofemoral joint requires that the patellar ridge accurately track the underlying trochlear groove when the knee is moved through flexion or extension.

Joint disorders nevertheless arise with varying severity, pain and
20 dysfunction. Some less severe, albeit still painful, disorders involve minimal or no errors in patellar tracking of the trochlear groove. Other more serious disorders are characterized by patellar subluxation, *i.e.*, transient displacement, or dislocation, *i.e.*, permanent displacement, of the patella from the trochlear groove.

Most frequently, such tracking errors occur in the lateral direction and
25 therefore require medial corrective traction. During functional movement of the knee joint, that is - typically from 0° to 60° of knee flexion, lateral tracking can occur due to injury, overuse, or changes inherent to adolescent growth, which in each of these cases causes pain and dysfunction. When the patella is seated in the trochlear groove at a range greater than about 60° of knee flexion, there is very
30 little movement of the patella outside of the trochlear groove. Between about 0° and 40° of knee flexion, and especially about 20° to 40°, however, there is a

propensity for the patella to track laterally as the knee flexes. As a result, effective medial traction forces must be applied in conjunction with exercise to direct the patella for improved tracking.

5 Rehabilitation of the weakened joint is therefore limited to the extent that true medial traction is absent, or ineffectively applied. While some devices may stabilize the patella, they fail to provide consistent, continuous traction force, and therefore fail to affect proper patellar tracking. It is important, moreover, to provide medial traction (and not mere stabilization) throughout a full range of knee flexion and extension motion.

10 In addition, biomechanical forces typically bias the patella laterally when the knee is load bearing. During knee extension, the quadriceps contract to exert a lever force about the patellofemoral joint, whereby the patella is pulled up along the trochlear groove. As the patella moves up the trochlear groove, the groove narrows, thereby forcing the patella to project more outwardly. Nearly
15 simultaneous application of load bearing pressure may result in either momentary or permanent lateral displacement of the patella such that medial traction must be used to correct or prevent the prevailing lateral subluxation or dislocation.

As the quadriceps contract, they apply a lever force to the patellofemoral joint that is, more or less, directly related to the overall patellofemoral joint stress.
20 Pain associated with such stress increases in relation to the amount of overall stress. Accordingly, as the quadriceps contract more powerfully, such as while going up stairs or doing squats, overall stress and associated pain increases.

However, patellofemoral joint stress at any given contact area decreases as the overall patellofemoral joint stress is distributed about a greater patellofemoral
25 contact surface area. Pain associated with such stress decreases in inverse relation to the amount of patella-to-femur contact surface area. Thus, patellofemoral pain is not only directly related to the overall joint force applied between the patella and the femur; it is inversely related to the amount of patellofemoral contact surface area. Rehabilitation of the weakened joint through
30 quadriceps contraction is therefore limited by the pain associated with both overall patellofemoral joint stress and a minimal patellofemoral contact surface area.

Because subluxation frequently occurs even early on in the extensor motion,

it is moreover important to account for the damage and pain caused by both overall joint stress and a minimal patellofemoral contact surface area, throughout a full range of knee flexion and extension motion.

Prior attempts to provide patellofemoral support fail to provide continuous medial tracking or account for patellofemoral contact surface area as a factor in joint stress. For example, United States patent no. 6,287,269 B1, entitled "Dynamic Orthosis Device for the Conservative Treatment of Patellofemoral Instability of the Knee", discloses a support element that provides medial tracking of the patella. Continued medial traction is absent, however, and it does not account for damage and pain caused by minimal patellofemoral contact surface area, however.

United States patents nos. 6,077,242 and 6,080,124, respectively entitled "Patella Strap" and "Patella Strap Method", disclose a strap that directs either superior or inferior, *i.e.*, downward or upward, pressure on a patella. Continued medial traction is absent, however, and it does not account for damage and pain caused by a minimal patellofemoral contact surface area, or provide medial tracking of the patella, however.

United States patent no. 6,592,539 B1, entitled "Orthotic or Prosthetic Sleeve Formed of Elasticized Fabric Sections Having Different Elastic Stiffness", discloses a compression sleeve having a section that fits over the entire knee and includes unidirectional stretchable fabric that stretches along the sleeve's axis. It does not account for damage and pain caused by a minimal patellofemoral contact surface area, or provide medial tracking of the patella, however.

United States patent no. 4,607,628, entitled "Patella Support Brace", discloses a patella pad that exerts a medial and distal pressure on the patella during knee extension. Continued medial traction is absent, however, and it does not account for damage and pain caused by minimal patellofemoral contact surface area, however.

United States patent no. 6,551,264 B1, entitled "Orthosis for Dynamically Stabilizing the Patello-femoral Joint", discloses a knee orthosis having a patellar tracking guide that tensions as the knee extends. It does not account for damage and pain caused by a minimal patellofemoral contact surface area, or provide

medial tracking throughout a full range of knee flexion and extension motion, however.

Hence, the prior art fails to provide a knee brace that provides medial traction and that accounts for pain caused by a minimal patellofemoral contact surface area throughout a full range of flexion and extension motion.

SUMMARY OF THE INVENTION

Thus, the present invention is directed to a knee orthosis that provides continued medial traction of a patella's lateral connective tissue.

10 The present invention is also directed to a knee orthosis that provides medial traction of a patella's lateral connective tissue throughout a full range of flexion and extension motion.

The present invention is also directed to a knee orthosis that provides direct inward pressure on a patella.

15 The present invention is also directed to a knee orthosis that provides inward pressure on a patella throughout a full range of flexion and extension motion.

The present invention is also directed to an orthotic method that provides continued medial traction of a patella's lateral connective tissue.

20 The present invention is also directed to an orthotic method that provides medial traction of a patella's lateral connective tissue throughout a full range of flexion and extension motion.

The present invention is also directed to an orthotic method that provides direct inward pressure on a patella.

25 The present invention is also directed to an orthotic method that provides inward pressure on a patella throughout a full range of flexion and extension motion.

One aspect of the present invention is directed to a knee orthosis that includes a medial tracking member that operatively fits along a lateral side of, and provides medial traction to, a patella having patellofemoral articular tissue; and an inward tracking member that operatively fits over, and provides inward pressure against, the patella; wherein the inward tracking member provides a compressive

force against the patella, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove.

In another aspect, the inward pressure is applied through an intermittent and progressively increased tightening of the inward tracking member.

5 In yet another aspect, the inward tracking member directly overlays the patella and the medial tracking member so that medial traction can be placed on the patella.

In still another aspect, the medial tracking member is adjustable to increase or decrease an amount of medial traction.

10 In yet another aspect, the inward tracking member is adjustable to increase or decrease an amount of inward pressure.

In still another aspect, the inward tracking member provides continuous compressive force against the patella throughout a full range of extension motion of an associated knee.

15 In yet another aspect, the continuous compressive force is substantially the same throughout the extension motion.

In still another aspect, the continuous compressive force increases throughout the extension motion.

20 In yet another aspect, the knee orthosis comprises a polycentric hinge having an axis that maintains a parallel position with respect to an associated knee throughout a flexion or extension motion of the knee.

In still another aspect, the polycentric hinge is bicentric and the inward tracking member is operatively attached to the hinge and aligned substantially perpendicular to the hinge axis.

25 In yet another aspect, the inward tracking member is mounted on the hinge, or operatively loops through a ring that is aligned parallel to the hinge axis.

In still another aspect, the knee orthosis comprises a breathable sleeve having attachment positions for anchoring and adjusting the medial tracking member and the inward tracking member.

30 In yet another aspect, the medial tracking member comprises a synthetic tube, a raised spacing member, or a raised extension member.

In still another aspect, the inward tracking member comprises an elastic,

adjustable strap.

Another aspect of the invention is directed to a knee orthosis that includes an inward tracking member that operatively fits over, and provides inward pressure against, a patella having patellofemoral articular tissue; wherein the inward
5 tracking member provides a compressive force against the patella, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral trochlear groove.

Another aspect of the invention is directed to an orthotic method for tracking a patella that includes applying a medial tracking member that operatively fits
10 along a lateral side of, and provides medial traction to, a patella having patellofemoral articular tissue; and applying an inward tracking member that operatively fits over, and provides inward pressure against, the patella; wherein the inward tracking member provides a compressive force against the patella as it inwardly tracks, thereby increasing the contact surface area between the
15 patellofemoral articular tissue and an associated femoral trochlear groove.

In another aspect, the inward pressure is applied through an intermittent and progressively increased tightening of the inward tracking member.

In still another aspect, the medial traction is applied through an intermittent and progressively increased tightening of the inward tracking member.

20 In yet another aspect, the medial traction applied through the intermittent and progressively increased tightening of the inward tracking member increasingly stretches lateral patellar connective tissue over time.

BRIEF DESCRIPTION OF THE DRAWINGS

25 In the accompanying drawings, which form a part of the specification and are to be read in conjunction therewith, and in which like reference numerals are used to indicate like parts in the various views:

FIG. 1 is front view of an attached knee orthosis, according to the present invention;

30 FIG. 1a is a medial-side view of the knee orthosis that, has vertically disposed medial tracking attachment positions, according to the present invention;

FIG. 2a is a side view of a laterally tracking patella and a partial distal side view of an associated lateral femoral condyle that, illustrates a relatively small point of contact between the patella and the lateral femoral condyle;

5 FIG. 2b is a frontal phantom view of a patellofemoral articulation positioned behind the medial tracking member and the inward tracking member of FIG. 1, according to the present invention;

FIG. 2c is a side view of a properly tracking patella and partial distal view of an associated femur that, illustrates the relatively large surface contact area after the patella receives inward compressive force, according to the present invention;

10 FIG. 3 is a lateral side view of the orthosis in FIG. 1;

FIG. 4 is a frontal view of an attached orthosis that has an alternate medial tracking member and the inward tracking member of FIG. 1, according to the present invention;

15 FIG. 5 is a frontal view of an attached orthosis that has another alternate medial tracking member and an alternate inward tracking member, according to the present invention;

FIG. 6 is a frontal view of the tracking member of FIG. 1; and

FIG. 7 is a lateral side view of a knee orthosis that has no mechanical hinge, according to the present invention.

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DETAILED DESCRIPTION OF THE INVENTION

As illustrated in the accompanying drawings and discussed in detail below, one aspect of the present invention is directed to a knee orthosis that, when used, provides continued medial traction to stretch out a patella's lateral connective
25 tissue. By allowing progressive, intermittent and repeated stretching of the patella's lateral connective tissue, it increases function and speeds rehabilitation.

The knee orthosis of this aspect also directs inward pressure on the patella to increase patellofemoral surface contact area. This inward pressure accordingly reduces the damage and pain associated with patellofemoral joint disorders by
30 evenly distributing the overall patellofemoral joint stress along a greater surface contact area, and thereby further speeds rehabilitation that would otherwise be hindered by greater pain and joint damage.

In one embodiment, the knee orthosis of the present invention provides medial and inward patellar traction. Referring to FIG. 1, knee orthosis 1 generally includes sleeve 10, medial tracking member 40, inward tracking member 60, and bicentric hinge 80.

5 Sleeve 10 slides into position and fits over the lower thigh, knee, and upper calf of right leg R. Sewn onto sleeve 10 are respective lateral and medial nylon webbing connection straps 12 and 14. Sleeve 10 is held in position by respective adjustable upper and lower elastic (or non-elastic, or combination thereof) attachment straps 16 and 18, which are sewn at their first ends 22 to hard plastic
10 buckles 24. Straps 16 and 18 wrap around the posterior and then the front of leg R, overlaying sleeve 10 and strap 14. Opposite ends 26 of straps 16 and 18 feed through respective buckles 24, which are positioned over strap 12, and back onto respective straps 16 and 18 to adjustably tighten and secure straps 16 and 18 with mating hook and loop material 28 and 29. Attachment straps 16 and 18 are held
15 into place by locking pins 19, which protrude through grommets 21, as seen in FIG. 1a.

Sleeve 10 is made of an elastic, breathable, compressive, synthetic material such as is disclosed in United States patent no. 5,735,807, which is hereby incorporated by reference in its entirety. Appropriate materials for sleeve 10 also
20 include, however, any synthetic or natural, elastic or inelastic, material suitable for use in a knee orthosis.

Referring again to FIG. 1, medial tracking member 40 comprises 3/8 inch silicone cord 44 covered by synthetic elastic material 46 of the type described in the previously mentioned '807 patent. Suitable coverings, however, can be made
25 from any stretchable or non-stretchable fabric. Upper and lower extension straps 48 and 50 are sewn onto both ends of cord 44 and feed through loops 52, which are sewn onto medial connection strap 14, and back onto themselves with mating hook and loop material 54 and 56 for adjustable tightening and attachment.

In an alternate embodiment, medial tracking member 40 can be further
30 adjusted at varying angles by replacing loops 52 with upper and lower, vertically disposed attachment positions 54 and 56, seen in FIG. 1a, having hook or loop material that corresponds to hook or loop material on extension straps 48 and 50.

This feature allows extensions 48 and 50 to be attached at various angles, in accordance with directional arrows X, in order to capture the lateral edge of the patella. Any attachment device suitable for attaching extension straps 48 and 50 can be used, however. Adjustable attachment length and angle of extension
5 straps 48 and 50 thus serves to anchor medial tracking member 40 and allow better capturing of the lateral edge of patella P.

In fact, the amount of traction caused by medial tracking member 40 can be adjusted and readjusted by the user as needed. This feature allows the user to effectively stretch out the lateral tissue of the patella that is inhibiting proper
10 movement of the patella with respect to the trochlear groove. Adjusting the traction of the patella improves the biomechanical functioning of the knee so that the knee can work more efficiently and powerfully as the quadriceps contract. The resulting better patellofemoral alignment reduces the pain in the joint by allowing a more powerful contraction of these muscles. This accordingly reduces user
15 rehabilitation time when the orthosis is worn.

Also effective for reducing rehabilitation time is the inward force exerted by inward tracking member 60, which fits directly over the patella and holds medial tracking member 40 in place so that medial traction can be placed on patella P. Referring to FIG. 3, inward tracking member 60 comprises an elastic strap that is
20 sewn onto ring 62, which is mounted onto hinge 80 such that its slot 64 is parallel to hinge 80's vertical axis A. Referring again to FIG. 1, end 66 overlays medial tracking member 40 and patella P, and feeds through opposing ring 68, which is mounted onto medial hinge 81, and folds back onto itself for adjustable tightening and securing with mating hook and loop material 70 and 72.

25 Inward tracking member 60 is made of synthetic elastic material, upon which is sewn hook 28 and loop 30 material. Thus, when tightened and secured, the elasticity of inward tracking member 60 provides a consistent and continuous compressive inward force upon the patella that is substantially the same throughout a full range of flexion and extension motions. It is thus the same from
30 about 0° to 60°, 0° to 20°, 20° to 40°, and 40° to 60° of knee flexion. Suitable materials for inward tracking member 60 include any material that can provide a continuous compressive force upon a patella that is substantially the same

throughout a full range of flexion and extension motions.

Inward tracking member 60 also provides continued medial and inward tracking, throughout the rehabilitation process. Referring to FIG. 2a, patella P is tracking laterally, which induces pain in the knee joint by putting an inordinate
5 amount of pressure on the a relatively small point of contact between patella P and lateral femoral condyle C.

Referring to FIG. 2b, placing inward tracking member 60 over patella P, and tightening it applies inward pressure to better position patella P in the trochlear groove. Over the course of rehabilitation, the user follows a protocol of tightening
10 inward tracking member 60 multiple times a day, thereby increasing both medial and inward traction on lateral tissues, which stretches and releases their tightness. Because these tissues cannot be completely stretched at all at once, an intermittent and progressively increased tightening is applied by readjustment of inward tracking member 60. Through such progressive tightening, inward tracking
15 member 60 provides consistent and continued medial traction and inward pressure.

Referring to FIG. 2c, ultimately this creates more surface contact area between patella P and femur F. Application of such an inward force has been contrary to historic thinking regarding treatment of patellofemoral issues.
20 Historically, it was thought that placing inward pressure on the patella would increase pain and wear out the articular tissue faster. Actually, the reverse is true.

Referring to FIG. 3, bicentric, hard plastic hinges 80 and 81 connect upper and lower upright hard nylon support members 84 and 86, which are inserted into respective lateral and medial connection straps 12 and 14. In particular, lateral
25 hinge 80 has hard plastic ring 62, which is mounted onto hinge 80 such that its slot 64 is parallel to hinge 80's vertical axis A. Thus, hinge 80 serves as an anchor for inward tracking member 60. Moreover, this configuration ensures that the horizontal disposition of tracking member 60 remains perpendicular to, and centrally disposed with respect to, the user's knee during knee flexion and
30 extension. Thus, suitable hinges include any unicentric and polycentric hinge that provides, or allows for, an inward tracking member 60 attachment slot that remains parallel to, and centrally disposed with respect to, the user's knee during knee

flexion and extension.

Referring to FIG. 4, in an alternate embodiment medial tracking member 110 comprises a raised spacing member that slidably attaches to, or clips underneath, and hangs beneath inward tracking member 60. Suitable materials for the abutting edge of spacing member 110 include foam, silicone or any other material that has a soft edge. Spacing member 110 itself can be made from any material suitable to provide medial traction. Medial tracking member 110 includes slot 112, or clips (not shown), through which member 60 feeds prior to adjustable tightening over patella P at vertical slot 114 in medial hinge 80 and fastening at end 116. Medial tracking member operatively abuts against lateral side of patella P and ring 118, which is mounted onto hinge 80, parallel to axis A.

Referring to FIG. 5, in an alternate embodiment medial tracking member 200 comprises a raised extension member that extends from hinge 80, and is drawn up against patella P by fitting elastic inward tracking member 230 over patella P. Medial tracking member 200 includes padded and raised, and specially contoured end 220, to which member 60 attaches. Suitable materials for end 220 include foam, silicone or any other material that has a soft edge. Medial tracking member 200 thus operatively abuts padded, contoured end 220 against the lateral side of patella P to provide medial traction, while inward tracking member 230 provides a continuous compressive inward force upon the patella that is substantially the same throughout a full range of flexion and extension motions.

Referring to FIG. 6, in an alternate embodiment, the orthosis of the present invention has inward tracking member 300 but does not have a medial tracking member. Inward tracking member 300 fits over patella P and provides inward force thereon. Inward tracking member 300 is made of synthetic elastic material of the type described in the previously mentioned '807 patent. Thus, when tightened and secured, inward tracking member 300 provides a continuous compressive force upon the patella that is substantially the same throughout a full range of flexion and extension motions. Suitable materials for inward tracking member 300 include any material that can provide a continuous compressive force upon a patella that is substantially the same throughout a full range of flexion and extension motions.

Referring to FIG. 7, in another alternate embodiment, the orthosis of the present invention has inward tracking member 60 but does not have a mechanical hinge *per se*. Rather, tracking member 60 is sewn onto, and fed through, loops 420, which are sewn onto respective lateral and medial straps 12 and 14. Hard
5 nylon uprights 430 and 440 are respectively sewn into upper and lower portions of straps 120 and 140 (140 not shown).

A second aspect of the present invention is directed to an orthotic method that includes applying a medial tracking member that operatively fits along a lateral side of, and provides medial traction to, a patella having patellofemoral articular
10 tissue. The method also includes the step of applying an adjustable inward tracking member that operatively fits over, and provides inward pressure onto, the patella. As a result, the inward tracking member provides a compressive force against the patella as it inwardly tracks, thereby increasing the contact surface area between the patellofemoral articular tissue and an associated femoral
15 trochlear groove.

Over the course of rehabilitation, the user follows a protocol of tightening inward tracking member 60 multiple times a day, thereby increasing both medial and inward traction on lateral tissues, which stretches and releases their tightness. Because these tissues cannot be completely stretched at all at once, an
20 intermittent and progressively increased tightening is applied by readjustment of inward tracking member 60. Through such progressive tightening, inward tracking member 60 provides consistent and continued medial and inward traction.

Other embodiments, as described above, can also be used in for this method.

25 While it is apparent that the illustrative embodiments of the invention disclosed herein fulfill the objectives of the present invention, it is appreciated that numerous modifications and other embodiments may be devised by those skilled in the art. Additionally, feature(s) and/or element(s) from any embodiment may be used singly or in combination with other embodiment(s). Therefore, it will be
30 understood that the appended claims are intended to cover all such modifications and embodiments that would come within the spirit and scope of the present invention.